

WHAT IS CLAIMED IS:

138(b) 1. A device for sealing a passageway in a human body, the device comprising:
12 a first anchor adapted to be placed proximate a first end of the passageway;
14 a second anchor adapted to be placed proximate a second end of the passageway; and
16 an elongate member adapted to extend through the passageway and connect the first and second anchors, the elongate member having a first end fixedly connected to the first anchor and a second end that releasably connects to the second anchor.

738(b) 2. The device of claim 1, wherein the passageway is a patent foramen ^{not limiting} ovale.

738(b) 3. The device of claim 1, wherein the first anchor includes a plurality of arms.

738(b) 4. The device of claim 3, wherein the plurality of arms extend from a central hub of the first anchor.

738(b) 5. The device of claim 1, wherein the elongate member is flexible.

738(b) 6. The device of claim 3, wherein the plurality of arms can assume a collapsed state and a deployed state.

738(b) 7. The device of claim 1, wherein the second anchor includes a plurality of arms.

09870813-060101
FOT090-ETB02860

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, D. C. 20005
202-408-4000

SECRET

a second anchor adapted to be placed proximate a second end of the passageway; and

738 (b) 23. A device for sealing a patent foramen ovale in a heart, the device comprising:

a first anchor including a first plurality of arms adapted to be placed proximate a first end of the patent foramen ovale;

a second anchor including a second plurality of arms adapted to be placed proximate a second end of the patent foramen ovale; and

a flexible elongate member adapted to extend through the patent foramen ovale and connect the first and second anchors, the elongate member having a first end fixedly connected to the first anchor and a second end that releasably connects to the second anchor, and wherein each of the first and second plurality of arms are collapsible from a deployed state to a delivery state.

738(b) 24. An assembly for sealing a passageway in a heart, the assembly comprising:

a positioning catheter capable of extending to the passageway; and
 a closure device capable of sealing the passageway, the closure device including a first anchor adapted to be placed proximate a first end of the passageway, a second anchor adapted to be placed proximate a second end of the passageway, and a flexible elongate member adapted to extend through the passageway and connect the first and second anchors,

wherein the closure device is positionable within the positioning catheter in a first collapsed state and extendable from the positioning catheter in a second deployed state.

738(b) 25. The assembly of claim 22, further comprising a guide catheter capable of extending to the passageway, and wherein the positioning catheter is capable of extending through the guide catheter.

26. The assembly of claim 24, wherein the second anchor includes a releasable fixation mechanism that releasably connects the second end of the elongate member to the second anchor.

27. The assembly of claim 26, wherein the positioning catheter includes a distal portion that selectively engages the releasable fixation mechanism.

28. The assembly of claim 27, wherein the distal portion includes an inflatable portion that selectively engages the releasable fixation mechanism.

29. The assembly of claim 28, wherein the inflatable portion includes a balloon.

38. The assembly of claim 35, wherein the gripping portion includes a movable grip attached to the biased portion.

39. The assembly of claim 38, wherein the gripping portion includes a fixed grip opposing the movable grip.

738(b) 40. The assembly of claim 24, wherein the passageway is a patent foramen ovale.

41. An assembly for sealing a patent foramen ovale in a heart, the assembly comprising:

a guide catheter capable of extending to the patent foramen ovale;

a positioning catheter capable of extending through the guide catheter to a position near the patent foramen ovale; and

a closure device capable of sealing the patent foramen ovale, the closure device including a first anchor having a first plurality of arms adapted to be placed proximate a first end of the patent foramen ovale, a second anchor having a second plurality of arms adapted to be placed proximate a second end of the patent foramen ovale, a flexible elongate member adapted to extend through the patent foramen ovale and connect the first and second anchors, and a releasable fixation mechanism that selectively engages a distal portion of the positioning catheter to releasably connect the second end of the elongate member to the second anchor,

wherein the closure device is positionable within the positioning catheter in a first state wherein each of the first and second plurality of arms are collapsed and extendable from the positioning catheter in a second deployed state wherein each of the first and second plurality of arms are extended.

00970001 00000000

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, D. C. 20005
202-408-4000

42. A method of sealing a passageway in a heart, comprising:
placing a first anchor proximate a first end of the passageway;
placing a second anchor proximate a second end of the passageway;

and

moving the second anchor relative to the first anchor along a flexible
elongate member disposed between the first and second anchors within the
passageway.

43. The method of claim 42, wherein placing the first anchor includes
expanding the first anchor from a collapsed state to a deployed state.

44. The method of claim 42, wherein the first anchor includes a plurality of
arms, and wherein placing the first anchor includes positioning the plurality of arms
proximate the first end of the passage.

45. The method of claim 42, wherein placing the first anchor includes
expanding the first anchor from a collapsed state to a deployed state.

46. The method of claim 42, wherein the second anchor includes a
plurality of arms and a sealing cover, and wherein placing the second anchor
includes positioning the plurality of arms and sealing cover proximate the second
end of the passage.

47. The method of claim 42, wherein the passage is a patent foramen
ovale (PFO).

48. The method of claim 47, wherein placing the first anchor includes
contacting the septum primum of the heart with the first anchor.

09370813.060101
T0T090*ETB02860

49. The method of claim 48, wherein placing the second anchor includes contacting the septum secundum of the heart with the second anchor.

50. The method of claim 42, wherein moving the second anchor includes holding a releasable fixation mechanism in an unfixed configuration.

51. The method of claim 50, wherein moving the second anchor further includes moving the second anchor towards the first anchor.

52. The method of claim 42, further comprising fixing the second anchor to the flexible elongate member.

53. The method of claim 52, further comprising severing the flexible elongate member adjacent the second anchor.

54. The method of claim 42, wherein a first end of the flexible elongate member is connected to the first anchor, and wherein placing the first anchor includes pulling proximally on the flexible elongate member to bring the first anchor into tight contact over the first end of the passage.

55. The method of claim 42, wherein the flexible elongate member passes through the second anchor, and wherein placing the second anchor includes pushing the second anchor in a distal direction to move the second anchor with respect to the flexible elongate member until the second anchor sealingly covers the second end of the passage.

738 (b) 56. A method of placing a closure device to seal a passageway in a heart, comprising:

advancing a catheter into a first end of the passageway and out a second end of the passageway;

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, D. C. 20005
202-408-4000

advancing a first anchor of a closure device out of a distal end of the catheter;

withdrawing the catheter through the passageway;

positioning the first anchor adjacent the second end of the passageway;

advancing a second anchor of the closure device out of the distal end of the catheter; and

positioning the second anchor of the closure device adjacent the first end of the passageway.

738(b) 57. The method of claim 56, wherein advancing the first anchor includes expanding the first anchor from a delivery configuration to a deployed configuration.

738(b) 58. The method of claim 57, wherein advancing the first anchor further includes advancing a flexible elongate member having a first end connected to the first anchor.

738(b) 59. The method of claim 58, wherein positioning the first anchor includes pivoting the first anchor with respect to the flexible elongate member.

738(b) 60. The method of claim 56, wherein the first anchor is connected to a first end of a flexible elongate member, and wherein positioning the first anchor includes pivoting the first anchor about the flexible elongate member.

738(b) 61. The method of claim 56, wherein advancing the second anchor includes expanding the second anchor from a delivery configuration to a deployed configuration.

0097031 050101
"ET802860"

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, D. C. 20005
202-408-4000

09870813 060101
FOI090 ET802860

62. The method of claim 61, wherein advancing the second anchor further includes advancing a flexible elongate member passing through the second anchor and having a first end connected to the first anchor.

63. The method of claim 62, wherein positioning the second anchor includes moving the second anchor along the flexible elongate member toward the first end of the passageway.

64. The method of claim 63, further comprising sealingly covering the first end of the passageway with the second anchor.

65. The method of claim 64, further comprising fixing the second anchor to the flexible elongate member subsequent to sealingly covering the first end of the passageway.

66. The method of claim 65, further comprising severing the flexible elongate member adjacent the second anchor after fixing the second anchor to the flexible elongate member.

67. The method of claim 56, further comprising testing the effectiveness of the positioning of the first anchor prior to advancing the second anchor.

68. The method of claim 67, wherein if the positioning is ineffective, re-advancing the catheter through the passageway to retrieve the first anchor.

69. The method of claim 56, further comprising testing the effectiveness of the positioning of the second anchor.

7386 } 70. A method of delivering a closure device to a patent foramen ovale in a heart, comprising:

advancing a catheter into the right atrium of the heart;

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, D. C. 20005
202-408-4000

advancing the catheter through the patent foramen ovale into the left atrium of the heart;

deploying a first anchor of the closure device in the left atrium;

withdrawing the catheter into the right atrium of the heart; and

deploying a second anchor of the closure device in the right atrium.

735(b) 71. The method of claim 70, further comprising positioning the first anchor within the left atrium prior to deploying the second anchor.

738(b) 72. The method of claim 71, wherein the first anchor is connected to a first end of a flexible elongate member, and wherein positioning the first anchor includes pivoting the first anchor with respect to the flexible elongate member.

739 73. The method of claim 72, wherein positioning the first anchor further includes pulling the flexible elongate member in a proximal direction to seat the first anchor against the septum primum.

740 74. The method of claim 72, wherein positioning the first anchor further includes pulling the flexible elongate member in a proximal direction to seat the first anchor against the septum primum and the septum secundum.

741 75. The method of claim 72, wherein positioning the first anchor further includes pulling the flexible elongate member in a proximal direction to seat the first anchor against the septum primum and to bring the septum primum into sealing contact with the septum secundum.

742 76. The method of claim 72, further including testing the effectiveness of the positioning of the first anchor prior to deploying the second anchor.

09870813.060101

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, D. C. 20005
202-408-4000

738(b) 77. The method of claim 70, wherein withdrawing the catheter into the right atrium of the heart includes deploying a flexible elongate member having a first end connected to the first anchor into the patent foramen ovale.

738(b) 78. The method of claim 70, wherein deploying the second anchor in the right atrium includes deploying the second anchor a substantial distance away from the septum secundum, such that the second anchor does not contact the septum secundum as it is deployed.

738(b) 79. The method of claim 70, wherein deploying the second anchor includes expanding the second anchor from a delivery configuration to a deployed configuration.

738(b) 80. The method of claim 70, wherein deploying the second anchor includes deploying a flexible elongate member passing through the second anchor and having a first end connected to the first anchor.

738(b) 81. The method of claim 70, further comprising positioning the second anchor.

738(b) 82. The method of claim 80, further comprising positioning the second anchor.

738(b) 83. The method of claim 82, wherein positioning the second anchor includes moving the second anchor along the flexible elongate member toward the septum secundum.

738(b) 84. The method of claim 83, wherein moving the second anchor includes advancing a positioning catheter connected to the second anchor.

09870813 060101
T0T090 ETB02860

0 85. The method of claim 84, wherein advancing the positioning catheter includes inflating a balloon in contact with a releasable fixation mechanism of the closure device.

738(b) 86. The method of claim 87, further comprising sealingly contacting the septum secundum with the second anchor.

738(b) 87 88. The method of claim 86, further comprising fixing the second anchor to the flexible elongate member subsequent to sealingly contacting the septum secundum.

0 88 89. The method of claim 87, wherein fixing the second anchor includes deflating the balloon in contact with the releasable fixation mechanism of the closure device.

89 90. The method of claim 88, wherein fixing the second anchor further includes piercing the flexible elongate member with at least one pin of the releasable fixation mechanism.

0 90 89 91. The method of claim 90, further comprising severing the flexible elongate member adjacent the second anchor after fixing the second anchor to the flexible elongate member.

91 738(b) 92. A method of sealing a patent foramen ovale with a closure device, comprising:

deploying a first anchor of the closure device in a left atrium of the heart;

bringing the first anchor into non-sealing contact with a first end of a passage forming the patent foramen ovale;

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, D. C. 20005
202-408-4000

deploying a second anchor of the closure device in the right atrium of the heart; and

bringing the second anchor into sealing contact with a second end of the passage to seal the patent foramen ovale.

93. A closure device for sealing a passageway in a heart, the device comprising:

a left atrial anchor configured to close a first end of the passageway;
a right atrial anchor configured to close a second end of the passageway; and

a flexible elongate member connecting the left and right atrial anchors, wherein the elongate member has a first end fixedly connected to the left atrial anchor and wherein the right atrial anchor is movable with respect to the elongate member and is configured to releasably attach to the elongate member at any one of a plurality of points along a length of the elongate member.

94. An assembly for sealing a passageway in a heart, the assembly comprising:

a guide catheter configured to extend from a point of entry into a body to the passageway; and

a closure device capable of sealing the passageway, the closure device including a first anchor adapted to be placed proximate a first end of the passageway, a second anchor adapted to be placed proximate a second end of the passageway, and a flexible elongate member connecting the first and second anchors;

09870813.060101

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, D. C. 20005
202-408-4000

wherein a first end of the elongate member is connected to the first anchor and wherein the elongate member extends through the second anchor and through the catheter to the point of entry into the body.

~~94~~ 95. A device for sealing a passageway in a human body, the device comprising:

a first anchor adapted to be placed proximate a first end of the passageway;

a second anchor adapted to be placed proximate a second end of the passageway; and

a flexible elongate member adapted to extend through the passageway and connect the first and second anchors, the elongate member capable of moving through the second anchor to vary a tension of the elongate member.

95 96. The device of claim 1, wherein the elongate member is a flexible braided structure.

96 97. The device of claim 1, wherein the elongate member is a flexible multifilar structure.

97 98. The assembly of claim 24, wherein the flexible elongate member is a braided structure.

98 99. The assembly of claim 24, wherein the flexible elongate member is a multifilar structure.

~~99~~ 100. A device for closing a passageway in a human body, comprising:
a first anchor adapted to be placed proximate a first end of the passageway;

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, D. C. 20005
202-408-4000

a second anchor adapted to be placed proximate a second end of the passageway; and

a flexible elongate member adapted to extend through the passageway and connect the first and second anchors, the elongate member having a first end releasably connected to the first anchor and a second end releasably connected to the second anchor.

~~100~~ 101. A device for closing a passageway in a heart comprising:

a left atrial anchor adapted to be placed in a left atrium of the heart and including a plurality of uncovered arms;

a right atrial anchor adapted to be placed in a right atrium of the heart and including a plurality of arms and a cover attached to the plurality of arms; and

a flexible elongate member adapted to extend through the passageway and connect the left and right atrial anchors, the elongate member having a first end fixedly connected to the left atrial anchor and a second end releasably connected to the right atrial anchor.

~~101~~ 102. A device for sealing a passageway in a heart, the device comprising:

a first anchor adapted to be placed proximate a first end of the passageway, the first anchor comprising a plurality of uncovered arms;

a second anchor adapted to be placed proximate a second end of the passageway, the second anchor comprising a plurality of uncovered arms; and

a flexible elongate member adapted to extend through the passageway and connect the first and second anchors, the elongate member having a first end

09870813 060101
101090 "ETB02860

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, D. C. 20005
202-408-4000

fixedly connected to the first anchor and a second end that releasably connects to the second anchor.

FOF090"ETB02860

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, D. C. 20005
202-408-4000